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| APPLICATION NO.               | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|--------------------|----------------------|---------------------|------------------|
| 10/577,655                    | 05/01/2006         | Kazuhiko Machida     | 0425-1257PUS1       | 3246             |
| 2252                          | 7590               | 06/04/2008           |                     |                  |
| BIRCH STEWART KOLASCH & BIRCH | EXAMINER           |                      |                     |                  |
| PO BOX 747                    | EPBS FORD, JANET L |                      |                     |                  |
| FALLS CHURCH, VA 22040-0747   | ART UNIT           |                      | PAPER NUMBER        |                  |
|                               | 1633               |                      |                     |                  |
|                               | NOTIFICATION DATE  |                      | DELIVERY MODE       |                  |
|                               | 06/04/2008         |                      | ELECTRONIC          |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                                       |                                       |
|------------------------------|---------------------------------------|---------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/577,655  | <b>Applicant(s)</b><br>MACHIDA ET AL. |
|                              | <b>Examiner</b><br>Janet L. Epps-Ford | <b>Art Unit</b><br>1633               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 May 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-16 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 4-5, drawn to DNA encoding a protein having 16-position hydroxylating enzymatic activity, partly or entirely or its variant, wherein:

A. The 16-position hydroxylating enzymatic activity is for macrolide compound 11107B, and is selected from the group consisting of:

1. A continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1;
2. A continuous nucleotide sequence from the base 420 to 1604 of SEQ ID NO: 2;
3. A continuous nucleotide sequence from the base 172 to base 1383 of SEQ ID NO: 3;
4. A variant of the sequences in 1-3 above, that hybridizes to the above sequences under stringent conditions, and encodes a protein having hydroxylating enzymatic activity for macrolide compound 11107B.
5. A degenerate variant of one of the sequences in 1-3 above.

B. The 16-position hydroxylating enzymatic activity is for macrolide compound 11107D.

Group II, claim 1, drawn to DNA encoding a protein having ferredoxin activity, partly or entirely or its variant.

Group III, claim 3, a protein encoded by the DNA of claim 2.

Group IV, claim 6, drawn to a method of isolating a DNA encoding a protein having enzymatic activity in hydroxylating the 16-position for macrolide compound 11107B.

Group V, claims 7 and 9-10, a DNA sequence encoding ferredoxin, or variant thereof, wherein:

A. The sequence is a continuous nucleotide sequence from the base 2564 to base 2761 of the sequence No. 1;

B. A continuous nucleotide sequence from the base 1643 to base 1834 of the sequence No. 2;

C. A continuous nucleotide sequence from the base 1399 to base 1593 of the sequence No. 3;

D. A DNA which is a variant of the DNA represented by the above (A-C);

(i) is hybridized with the DNA described in the above (d) under a stringent condition; and  
(ii) encodes a protein having a ferredoxin function.

E. A degenerate variant of the DNA in (A-C), and does not hybridize to these sequences under stringent conditions.

Group VI, claim 8, a ferredoxin protein encoded by the DNA as in claim 7.

Group VII, claim 11, drawn to a method of isolating a DNA encoding a protein having a ferredoxin function.

Group VIII, claim 12-16 drawn to a method of producing a 16-position hydroxyl macrolide compound comprising culturing a transformant that expresses a DNA encoding a protein having enzymatic activity in hydroxylating the 16-position for macrolide compound 11107B, or variant thereof.

Group IX, claim 12, 14-16 drawn to a method of producing a 16-position hydroxyl macrolide compound comprising culturing a transformant that expresses a DNA encoding a ferredoxin protein, or a variant thereof.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-IX share a technical relationship drawn to a nucleic acid sequence encoding a ferredoxin protein. This relationship does not constitute a special technical feature since it does not make a contribution over the prior art. Document WO2003-040370 A1 describes a protein

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having the capability of metabolizing a weed control active compound. This protein is a ferredoxin and has homology of about 80-90% with the base sequences of sequence 1-3 of the present application. Therefore, the DNA that encodes, in part or as a whole, a protein having 16-hydroxylase activity or a ferredoxin used in a production wherein a specific macrolide derivative is converted into a 16-hydroxylated macrolide compound could be easily be conceived of by an expert of skill in the art by following the teachings of the cited document.

3. Moreover, see 37 CFR 1.475(c), which states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)."

Instant Groups I-IX are drawn to multiple distinct products and methods, the instant claims read on multiple categories of invention, therefore the instant groups which set forth the various products and groups recited in the claims are determined to lack unity of invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

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not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. With the election of Group VIII or IX, a species election of the plurality of compounds encompassed by formulas (III), (III-a), (IV) and (IV-a) will also be required for search purposes.

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Formulas (III), (III-a), (IV) and (IV-a) each represent a genus of compounds each formula encompasses an exponential number of structurally distinct compounds, which require a separate search and consideration of the prior art. Applicants are required to elect a single species from formulas (III), (III-a), (IV) and (IV-a) for search purposes.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The claims are deemed to correspond to the species listed above in the following manner:

Claims 12-13 recite the formulas III and IV, claims 14-15 recite the formulas III-a, and IV-a.

The following claim(s) are generic: Claims 1-11 and 16 are generic with respect these formulas.

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The individual species defined in formulas (III), (III-a), (IV) and (IV-a) lack any corresponding special technical features as they are drawn to multiple products, and therefore read on more than one category of invention. The species defined above lack unity of invention for the reasons set forth above.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633

JLE